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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,129	10/14/2003	Guy W. Miller	13682.2USC1	7630

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EXAMINER	
POLANSKY, GREGG	
ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
12/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/686,129	MILLER, GUY W.	
	Examiner	Art Unit	
	Gregg Polansky	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) *1-22,24-29 and 38-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23,30-37 and 46-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/20/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Applicant's Information Disclosure Statement, filed 10/24/2004, is acknowledged and has been reviewed to the extent each is a proper citation on a U.S. Patent.

2. Applicant's election without traverse of Group II (Claims 23, 30-37, and 46-49) in the reply filed on 10/20/2004 is acknowledged. The Restriction Requirement is thus deemed to be proper and is made Final.

3. Claims 1-49 are pending.

4. Claims 1-22, 24-29, and 38-45 are withdrawn from consideration because they are contained in non-elected groups. 37 CFR 1.142(b).

5. Claims 23, 30-37, and 46-49 are presently under consideration.

6. All claims under consideration are regarded to be composition claims.

Priority

7. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the

requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60,284,389, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Application No. 60,284,389 fails to provide support for instant Claims 32-34 and 46-49.

Specification

8. The use of the trademark AUREOMYCIN, AUREOMIX, BMD, CHLOMAX, DENAGARD, LINCOMIX, MECADOX, NEO-TERRAMYCIN, PULMOTIL, TYLAN and others have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 23, 30, 31, 33 and 35-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Teiji (Japanese Patent Publication No. 03-076561, Abstract Only). Oku et al. (Pure and Applied Chemistry, Vol. 74(7), pages 1253-1261) is provided for evidentiary purposes.

Teiji teaches a digestion-resistant, enterobacterium (e.g., *Bifidobacerium*) containing capsule, coated with fructooligosaccharide, used to administer the bacterium to the colon without inactivating said bacterium by gastric fluids. See Abstract.

Oku et al. teach neosugar as another name for fructooligosaccharide. See page 1255, 2nd line.

Intended use confers no patentable weight to composition claims. *In re Hack*, 114 USPQ 161.

11. Claims 23, 30, 31, 34-37, and 48 are rejected under 35 U.S.C. 102(a) as being anticipated by Sotoyama et al. (U.S. Patent No. 6,451,344 B1).

Sotoyama et al. teach a tablet comprising a core coated with lactulose and raffinose. The core of said tablet comprises *inter alia Lactobacillus* and *Bifidobacterium*. See column 12, claims 1 and 2. Sotoyama et al. teach lactulose and raffinose are fructose-based sugars. See column 1, last 2 paragraphs. The reference teaches that

additional coating agents known in the art can be used, including powdered glucose, to enhance the properties of the tablet, including its flavor and mouth feel. See column 5, 3rd paragraph, and column 10, "Example 1".

12. Claims 23 and 30-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Leusner et al. (U.S. Patent 6,468,568 B1).

Leusner et al. teach mineral or vitamin encapsulated by fructooligosaccharides or inulin for controlled release. See Abstract, and column 20, "Example 1", column 21, claim 1, and column 22, claim 13.

13. Claims 23, 30, 31, 35-37, and 48 are rejected under 35 U.S.C. 102(e) as being anticipated by Toyama et al. (Japanese Patent No. 2001048808, Abstract only).

Toyama et al. teach enteric coated tablets comprising a core containing *Bifidobacterium*, and a coating of lactulose and raffinose. See Abstract.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 23, 30-37, and 46-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Teiji (Japanese Patent Publication No. 03-076561, Abstract Only), in view of Takaichi et al. (U.S. Patent No. 6,750,331,B1).

As previously presented (*supra*), Teiji teaches a digestion-resistant, enterobacterium (e.g., *Bifidobacerium*) containing capsule, coated with fructooligosaccharide.

Teiji does not teach *per se* a soya oligosaccharide, stachyose (a soya oligosaccharide), lactulose or galactooligosaccharide, or a flavoring component of the coating.

Takaichi et al. teach *inter alia* oligosaccharides which are undigested with human digestive enzymes and are utilized by *Lactobacillus bifudus*; these oligosaccharides include fructooligosaccharide, lactulose, galactooligosaccharide, and soybean oligosaccharide. See column 3, 1st paragraph.

One of ordinary skill in the art at the time of the invention would have found it obvious to substitute one known digestion-resistant oligosaccharide for another. One would have been motivated to do so to optimize the coating for its intended use. Adding a flavoring agent, as needed, would have been routine to the artisan to produce a more palatable product.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the

claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

16. Claims 23, 30-37, and 46-49 are rejected.

17. No claims are allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregg Polansky whose telephone number is (571) 272-9070. The examiner can normally be reached on Mon-Thur 8:30 A.M. - 7:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gregg Polansky

Phyllis Spivack 12/6/07

PHYLLIS SPIVACK
PRIMARY EXAMINER